

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
HEALTH  
ORGANIZATION



JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 3 (b)

CX/FICS 06/15/4

August 2006

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME  
CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION  
AND CERTIFICATION SYSTEMS**

**Fifteenth Session**

**Mar de Plata, Argentina, 6-10 November, 2006**

**PROPOSED DRAFT APPENDIX TO THE CODEX GUIDELINES ON THE JUDGEMENT OF  
EQUIVALENCE OF SANITARY MEASURES ASSOCIATED WITH FOOD INSPECTION AND  
CERTIFICATION SYSTEMS**

**(AT Step 3)**

**(Prepared by the United States with the assistance of Antigua and Barbuda, Argentina, Australia, Brazil, Burundi, Canada, Chile, Denmark, Ecuador, European Community, Finland, France, Guatemala, India, Iran, Italy, Japan, Kenya, Malaysia, Netherlands, New Zealand, Norway, Philippines, Republic of Korea, Romania, Rwanda, South Africa, Switzerland, Thailand, Consumers International and IAFI)**

Governments and international organizations wishing to submit comments on the following subject matter are invited to do so **no later than 15 September 2006** to: Codex Australia, Australian Government Department of Agriculture Fisheries and Forestry GPO Box 858, Canberra ACT, 2601 (fax: 61.2.6272.3103; E-mail: [codex.contact@affa.gov.au](mailto:codex.contact@affa.gov.au)), with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Via delle Terme di Caracalla, 00100 Rome, Italy (Fax No + 39.06.5705.4593; E-mail: [codex@fao.org](mailto:codex@fao.org)).

## **BACKGROUND**

1. At its 12<sup>th</sup> Session, CCFICS recommended<sup>1</sup>, and the Commission agreed that new work be undertaken on proposed draft appendices to the adopted *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification* (CAC/GL - /2003). The Committee's Project Document stated that the following main aspects would be covered in the proposed new work.

1. Assessing which measures are to be the subject of an equivalence determination;
2. Documentation for evaluation of submissions of requests for equivalence determinations;
3. Terms for on-site visits by importing country authorities undertaking a determination of equivalence;
4. Determining an "objective basis of comparison";

<sup>1</sup> ALINORM 04/27/30, para 88(a).

5. More detail on the process of judging equivalence; and
  6. Information relating to technical assistance to be provided by importing countries to exporting countries;
2. Over the next two Sessions CCFICS, considered Discussion Papers<sup>2</sup> prepared by the United States with the assistance of a working group. While, originally, the Committee proposed that work on the various appendices should be carried out in a step-wise fashion, at its 14<sup>th</sup> Session, CCFICS observed that certain elements of each of the five proposed appendices were needed to understand the others and that it might be better, both for logic flow and to avoid duplication, to develop a single combined appendix.
3. The Committee also agreed that: 1) to the extent possible, each section of the combined appendix should be referenced to corresponding paragraph(s) of the main document; 2) the appendix should clearly distinguish procedures for the determination of equivalence of a single measure and of an inspection system; 3) the physical Working Group should take into account the written comments submitted and the comments made at the 14<sup>th</sup> Session, as well as the draft structure contained in CRD 16, and 4) elements on technical assistance as presented in the *Discussion Paper on the Development of an Appendix on "Information Relating to the Need for Technical Assistance and Cooperation Between the Importing Countries to Exporting Countries" to the Codex Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification*<sup>4</sup> should be considered for inclusion in the Appendix. The Committee agreed to return the document to Step 2 for redrafting as a single combined appendix by a Working Group led by the United States.
4. The United States, as the lead for the Working Group, prepared and circulated electronically for comment to the Working Group a revised paper based on comments submitted to CCFICS at its 14<sup>th</sup> (2005) Session and the discussion that occurred at that Session<sup>3</sup>. The revised paper had been reorganized substantially and based on the request of the committee, combined all previously-prepared annexes into a single annex. The Paper also contained initial drafts for those subjects agreed to in the project document and not originally developed, specifically "identifying which measures are to be the subject of an equivalence determination" and "terms for on-site audits". The paper also incorporated considerations on technical assistance with respect to equivalence determinations, previously developed and presented to the Committee in the *Discussion Paper on the Development of an Appendix on "Information relating to the need for technical assistance and cooperation between the importing country to the exporting country to the Codex Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification"*<sup>4</sup>. The Working Group, met in Brussels, June 22-27, 2006 at the kind invitation of the European Commission. Participants to the Working Group are shown in Attachment 2. The Working Group considered the revised Paper along with comments submitted electronically by the Working Group<sup>5</sup>.
5. The Working Group revised the text substantially, considering a large number of key items including the following.
- The scope of the document, particularly whether the Annex should consider determining equivalence of only specific measures or whether the scope should be broader involving consideration of the entire food safety system including: infrastructure; program design, implementation, and monitoring; and specific requirements. While a few delegations believed the scope should be narrow, focusing only on an elaboration of paragraph 18 of the main document, most delegations believed the scope should be broad; that is, the Annex should consider the situation when it might be required that many elements comprising a food safety system may have to be considered in undertaking a determination of equivalence. This issue of scope arose frequently during the meeting and impacted on several aspects of the discussion.

---

<sup>2</sup> CX/FICS 04/13/3, CX/FICS 05/14/3

<sup>3</sup> ALINORM 06/29/30, paras 10-17

<sup>4</sup> CX/FICS 05/14/8

<sup>5</sup> Brazil, Canada, European Community, and India had submitted comments

- Clarifying whether the process of undertaking an equivalence determination would initially include an indication of those measures of the food safety system with which a country will comply in addition to those for which it is seeking a determination. This was noted to be essentially an aspect of the scope of the determination noted above. The notion of considering all measures encompassing the food safety system associated with the food product(s) under consideration, both those with which an importing country will comply and those for which it seeks an equivalence determination was included in the document.
- How the importing country's experience, knowledge, and confidence of the exporting country's food safety systems is utilized in the determination of equivalence, particularly with respect to determining which measures are to be the subject of an equivalence determination. The use of experience, knowledge and confidence was included within the document, recognizing that this aspect was, again, an aspect of the scope discussion.
- The extent to which the Appendix should address the need for a rationale for undertaking a determination of equivalence, as well as other factors that should initially be considered before undertaking an equivalence determination. Aspects considered at some length included trade facilitation, whether means other than equivalence (e.g., compliance) can achieve the desired objective, the availability of data and resources required to undertake an equivalence determination, and the benefits of an equivalence determination to the importing country. The Working Group agreed to include a brief section noting these aspects.
- Whether examples of an "Objective Basis of Comparison" (OBC) were necessary or whether the meaning and usage of OBCs could be conveyed through narrative text only. While different views were expressed on this matter, the Working Group agreed that, at least for the present, examples would be maintained, recognizing the importance and complexity of this aspect of the document. The Working Group had time only to discuss two of the four examples included in the text and left the final two examples in square brackets. The Working Group also noted that further discussion of the need for examples, and the precise nature and type of examples, should they be included in the Appendix, would be necessary. In discussing OBCs the Working Group noted that any reference to the use of Food Safety Objectives, Performance Objectives, or Performance Criteria in relation to OBCs needs to be carefully considered as these aspects are still under development within the context of Codex.
- The issue of on-site visits and the fact that such visits were to be conducted solely with respect to verifying aspects of the equivalence determination and not expand into broader aspects of the performance of a country's food inspection systems.
- Whether, and the extent to which, a section on technical assistance should be included in the Appendix. Views varied widely in this regard, extending from maintaining the section in its present form (essentially as a set of principles) to expanding or deleting it. The Working Group also expressed a range of views as to whether appropriate technical assistance with respect to equivalence should be limited to the scientific/technical aspects associated with a specific equivalence determination or deal more broadly with such areas as regulatory and food sector infrastructure. The Working Group agreed to retain the section in its present form pending consideration by the Committee. The Chairperson of CCFICS noted the possibility of holding a workshop immediately prior to the 15<sup>th</sup> Session of the Committee to discuss the area of technical assistance with respect to equivalence determinations and the nature and extent to which it should be included in the Appendix.

## RECOMMENDATION

The Committee is invited to consider the attached proposed draft appendix to the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification* (Attachment 1) with a view towards their further progression in the Codex Step Procedure.

**Attachment 1****PROPOSED DRAFT APPENDIX****FURTHER GUIDANCE TO ASSIST IMPORTING AND EXPORTING COUNTRIES IN IMPLEMENTING THE CODEX GUIDELINES ON THE JUDGEMENT OF EQUIVALENCE OF SANITARY MEASURES ASSOCIATED WITH FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS (CAC/GL 53-2003)****INTRODUCTION AND PURPOSE**

1. This appendix provides further guidance on:
  - identifying which measures<sup>1</sup> are to be the subject of an equivalence determination;
  - documentation for determination of equivalence of measures ;
  - determining an objective basis of comparison;
  - the process of judging equivalence (including terms of reference for on-site visits by importing country authorities undertaking a determination of equivalence; and experience, knowledge and confidence in the exporting country's food inspection and certification system); and
  - technical assistance with respect to equivalence determinations.
2. The exporting country should initiate an official request for the determination of equivalence, including identifying the food products or group of food products concerned.
3. The initial communications between the two countries should include exchange of contact information for the respective competent authorities to facilitate future information exchanges (e.g., contact person, address, phone, and e-mail, facsimile).
4. Information may be exchanged between the exporting and importing country during any stage in the equivalence determination process using tools, such as a questionnaire, that facilitate an organised compilation of material and subsequent equivalence determination.

**IDENTIFYING WHICH MEASURES ARE TO BE THE SUBJECT OF AN EQUIVALENCE DETERMINATION**

5. Before identifying measures to be the subject of an equivalence determination, the exporting country should consider its rationale or purpose for, and other factors that relate to, the proposed request for an equivalence determination. The exporting country may consider:
  - The availability of data to support an equivalence determination;
  - Whether there is a need for facilitation of trade while ensuring the protection of health of consumers;
  - Current international standards and texts;
  - Resources necessary to proceed through the equivalence process;
  - Whether the purpose may be more easily or quickly achieved through a different mechanism (e.g., meeting importing country requirements);
  - Possible benefits of an equivalence determination to the importing country.

---

<sup>1</sup> In all cases the word “measure” is taken to refer to sanitary measures

6. The exporting country should then identify the sanitary measures of the importing country for which an equivalence determination is sought. The exporting country should:
  - Identify and document its own sanitary measure(s)<sup>2,3</sup> associated with the food product or group of food products;
  - Where relevant, request the competent authority in the importing country to provide the nature and purpose of its sanitary control measures associated with the food product or group of products<sup>4</sup>;
  - Determine those sanitary measures of the importing country with which the exporting country will comply and those for which it proposes to seek equivalence of its sanitary measures
7. In some cases, it may be useful to carry out a side-by side comparison of measures between systems. Such a comparison, in consultation with the importing country, should promote better understanding of each country's measures and the measures' purposes and, thus, enable the exporting country to identify the measures for which a determination of equivalence will be sought.

### **DOCUMENTATION FOR DETERMINATION OF EQUIVALENCE OF MEASURES<sup>5</sup>**

8. Once the exporting country has indicated to the importing country its intent to seek equivalence of specified sanitary measures and has requested the reason/purpose and objective basis of comparison (see next section) of the measures, as needed, the exporting country will be ready to prepare its documentation for submittal to the importing country. In doing this, a dialogue is likely to be needed between the two countries, for example, to:
  - seek clarification by the importing country of the request being made by the exporting country; and,
  - seek clarification by the exporting country as to the requirements of the submittal package.

#### **Submittal Package**

9. Documentation provided by the competent authority of the exporting country to the importing country should:
  - a) clearly articulate the request for a determination of equivalence, and identify the food product or group of food products involved and the sanitary measure(s) that are to be the subject of the equivalence determination;
  - b) clearly identify the importing country's sanitary measure(s) to which the exporting country seeks an equivalence determination ;
  - c) provide documentation (for example, risk assessment, side-by-side comparison of specified measures, data) that the alternative sanitary measure(s) identified by the exporting country is/are equivalent to the measure(s) of the importing country; and,
  - d) provide documentation on the existence of the exporting country's legislative base and administrative systems for implementing and enforcing the alternative sanitary measure(s).
10. Factors affecting the detail and extent of the documentation provided in the submittal package may include:
  - a) the number and nature of the sanitary measure(s) to be the subject of the equivalence

---

<sup>2</sup> Hazard and measure may be singular or plural.

<sup>3</sup> See note under the definition of sanitary measure in Section 3 of the main document.

<sup>4</sup> This information may be available, for example, as part of the importing country's legislation, or in its standards, regulations, codes of practice, or policy guidelines.

<sup>5</sup> Additional guidance elaborating section 7 of the main document.

determination; and,

- b) the experience, knowledge and confidence that an importing country has with respect to an exporting country's food inspection and certification system, including details of any existing trade.
11. Once the submittal package is received by the importing country, the competent authorities in the importing and exporting countries should use a mutually agreed process, including a timeframe for considering the request for a judgement of equivalence.

#### **DETERMINING AN "OBJECTIVE BASIS OF COMPARISON"<sup>6</sup>**

- 12. The OBC is the means by which alternative measures or groups of measures can be shown to achieve the same effect, relative to the achievement of the importing country's ALOP, as the corresponding sanitary measures applied by the importing country and, therefore, may be considered equivalent.
- 13. Depending upon the nature and extent of the measures subject to an equivalence determination, one or more OBCs may be needed to effectively evaluate alternative sanitary measures or groups of sanitary measures. For example, more than one objective basis of comparison may be required where a single measure applied by an importing country contributes in several different ways (e.g., controlling multiple hazards) to the achievement of the ALOP. Also, in the case of a food control system utilizing multiple measures to control multiple hazards, multiple OBCs may be needed.

#### **Elements or Criteria for Developing an Objective Basis of Comparison**

- 14. An OBC may be quantitative and/or qualitative in nature.
- 15. Developing a quantitative OBC may require data gathering and statistical analysis that leads to development of a measurable OBC. Developing a qualitative basis of comparison may also require data gathering and may include using appropriate subject matter experts, who can provide information to assist in judgements on the comparability of alternative measures.
- 16. The importing country should gather and assess scientific data and other information<sup>7</sup> to develop an OBC and enter into a dialogue with the exporting country to seek agreement on the OBC. This process should, as appropriate:
  - a) Ensure sufficient data to provide valid support for conclusions;
  - b) Ensure the adequacy and accuracy of the data;
  - c) utilize risk assessments, as available; and
  - d) Utilize side-by-side comparisons of the data developed by the importing and exporting countries associated with the same or alternative measures.
- 17. Potentially, all measures associated with infrastructure, program design, implementation and monitoring, and specific requirements may be the subject of an equivalence determination and may require the development of an objective basis of comparison. Examples of measures for which an OBC may be required and/or that could be used to reach agreement on an objective basis of comparison include:<sup>8</sup>
  - a) **Infrastructure measures:**
    - legislation in place, e.g., food and enforcement laws, decrees, regulations, directives;

<sup>6</sup> Additional guidance elaborating Section 6 of the main document.

<sup>7</sup> In the context of this appendix data is taken to mean both quantitative and qualitative data and other information

<sup>8</sup> Section 6 of the *Codex Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997) can provide a useful basis for identification and development of elements or criteria for an objective basis of comparison for infrastructure measures and program design, implementation and monitoring measures.

- structure or system of national or regional authorities;
- laboratory/testing infrastructure; and
- compliance/enforcement programs;

**b) Program design, implementation and monitoring measures**

- requirements for good manufacturing practices (GMPs), good hygienic practices (GHPs) and and/or Hazard Analysis and Critical Control Point (HACCP) systems;
- documented decision criteria and action plans demonstrating that compliance/enforcement programs are targeted at the most appropriate stages and operations to deliver the desired outcome;
- laboratory and analyst proficiency programs: methods validation programs; and
- training and certification programs

**c) Specific requirement measures**

- Maximum residue limits (MRLs);
- [performance criteria (e.g.,) a specified log reduction in a bacterial pathogen in a food];
- [performance objective (e.g.,) less than x organisms in y amount of a food at a specific point in the processing chain];
- process criteria (e.g., time and/or temperature requirements, water activity)
- methods of sampling and inspection; and,
- microbiological methods used for monitoring of pathogens.

19. Examples of objective bases of comparison include the following:

[**Note:** the following examples are provided as a starting point for discussion and use a consistent format to present examples of OBCs.]

**JUICE PROCESSING TO REDUCE BACTERIAL PATHOGENS**

**Importing Country Sanitary Measure:** Fruit juice processors are required to use processes that achieve a 5 fold or 100,000 reduction in the numbers of the most resistant pathogen in their finished product compared to levels that may be present in the untreated juice.

**Reason/Purpose for the importing country's sanitary measure:** to assure that fruit juices do not present unacceptable levels of food borne pathogens that may cause illness in consumers.

The OBC is the level of the most resistant pathogen that would achieve the importing country's level of hazard control, which is achieved in the importing country through the 5 log reduction (i.e. X number of pathogens per Y volume of processed juice).

**SAMPLE COLLECTOR:** exporting country utilises third parties for sample collection and importing country uses government employees.

**Importing Country Sanitary Measure:** Government employees collect ready-to-eat) product samples for *Listeria* testing according to importing country standard procedures.

**Reason/purpose for the importing country's sanitary measure:** To ensure sample collection integrity and reliability under the RTE *Listeria* program.

**OBC:** Controls to ensure competency and lack of conflict of interest of sample collectors. For example;

- There is a clearly written sampling plan with instructions for sample collection.
- The government has a means of ensuring that sample collection activities are in accordance with the intent and procedures of the sampling plan.

- Sample collectors have received appropriate training and there are adequate provisions to avoid conflicts of interest.

### LABORATORIES

**Importing Country Sanitary Measure:** Government laboratories analyse ready-to-eat product samples for the presence of *Listeria*.

**Regulatory or Food Safety Objective:** To ensure the integrity and reliability of sample analysis under the RTE *Listeria* testing program.

**OBC:** Criteria used for equivalence decisions for exporting country's use of private laboratories in lieu of government laboratories:

- The laboratory must be accredited/approved by the government, accredited by a third party accrediting organization with oversight by the government, or a government contract laboratory.
- The laboratory must have properly trained personnel, suitable facilities and equipment, a written quality assurance program, and reporting and recordkeeping capabilities.
- Results of analyses must be reported to the government or simultaneously to the government and establishment.

### ANALYTICAL METHODS

**Importing Country Sanitary Measure:** Methods approved for the testing of ready-to-eat meat and poultry products for *Listeria monocytogenes* must include an enrichment step and enable the detection of less than one colony-forming unit per gram of tissue in a 25-g sample.

**Regulatory or Food Safety Objective:** To ensure that ready-to-eat meat and poultry products meet the Importing Country's tolerances for *Listeria monocytogenes*.

**OBC:** The criteria used for determining whether a different testing method used by an exporting country is equivalent are as follows:

- The method must detect less than one colony-forming unit per gram of *Listeria monocytogenes* in a 25 gram sample of ready-to-eat product.
- The method is a scientifically validated method of analysis for *Listeria monocytogenes* approved or adopted by an internationally recognized organization.]

20. Once an objective basis of comparison has been agreed and documented, the exporting country, if it wishes to proceed, should then develop the documentation to be presented to the importing country for a determination of equivalence.

### MORE DETAIL ON THE PROCESS OF JUDGING EQUIVALENCE<sup>9</sup>, INCLUDING TERMS FOR ON-SITE VISITS<sup>10</sup>

#### **On-going dialogue<sup>11</sup>**

21. An on-going dialogue between the importing and exporting countries will need to occur during the consideration by the importing country of the request for an equivalence consideration by the exporting country to, among other things, clarify technical points and respond to the need for additional information.

#### **Experience, Knowledge and confidence<sup>12</sup>**

<sup>9</sup> Additional guidance elaborating Sections 7 and 8 of the main document.

<sup>10</sup> Additional guidance elaborating on paragraph 7, k) of the main document.

<sup>11</sup> Additional guidance elaborating on the need for dialogue indicated in Figure 1 (simplified flow chart for the determination of equivalence). Also see paragraph 8 of this Appendix.

<sup>12</sup> Additional guidance elaborating paragraphs 10-12, and 20(a) of the main document.



22. Judgement of equivalence of measures may be expedited by experience, knowledge and confidence in the food inspection and certification system of the exporting country, based on the information/documentation available to the importing country in its own records or those supplied by the exporting country. Where further information is required by the importing country this will be contained in the submittal package (refer to paragraphs 9-11).
23. Experience, knowledge and confidence in an exporting country's food inspection and certification system by an importing country may include the history of food trade between the two countries and the history of compliance of foods with the importing country's requirements, particularly the food products involved in the equivalence determination. Other factors include:
  - a. general knowledge of the exporting country's food safety system as demonstrated by, among other things, a side by side comparison;
  - b. results of audits/inspections/field examinations by the importing country, other countries, or other officially recognized third party organizations;
  - c. information on the exporting country's application and implementation of the risk analysis framework in the food safety system;
  - d. available exporting country risk assessments;
  - e. port of entry inspection and test results, including records of import rejections and alerts by the importing country as well as from other trading partners;
  - f. agreements the importing country may already have with the exporting country, including equivalence agreements;
  - g. bilateral or multilateral agreements on recognition of equivalence with other countries;
  - h. historical data regarding the importation and compliance of other food or groups of food products from the same country;
  - i. frequency of organisational/structural/administrative changes in the exporting countries competent authority/ies;
  - j. contingency plans for containing and mitigating the effects of food safety emergencies;
  - k. food borne disease surveillance data associated with the food product;
  - l. the degree to which industry in the exporting country uses appropriate processing controls;
  - m. adequacy of the exporting country's legislation and, as appropriate, quality control systems;
  - n. level/form of oversight of the food production system by the exporting country's certifying authority;
  - o. acknowledgement and evaluation of pre-existing certification systems conducted or carried out by the exporting country.
  - p. any specific export control system in operation.
24. An importing country can apply such experience, knowledge and confidence to:
  - a. assist in making a decision as to whether and how to proceed with a request for a judgement of equivalence;
  - b. assist in setting priorities, as may be appropriate;
  - c. confirm, or not confirm, the conclusions of the exporting country's side-by-side comparison of its relevant sanitary measures with the importing country's sanitary measures;
  - d. narrow the scope of the sanitary measures that are to be the subject of the equivalence determination;
  - e. limit the need for seeking further scientific evidence to that necessary to determine equivalence,

bearing in mind the economic implications<sup>13</sup>.

- f. [determine the extent to which equivalence may be judged without the need for any further work.; determine the necessity or scope of an on-site visit by the importing country of the exporting country's system];
  - g. formally recognize existing trade relationships with an exporting country.
25. In applying experience, knowledge and confidence to a determination of equivalence, transparency is essential so that the use and application of this information is clear to all parties.

#### **On-site Visits<sup>14</sup>**

26. On-site visits may be useful in the determination of equivalence to verify information contained in the submittal package. The rationale for on-site visits related to the determination of equivalence may include:
- a. To help verify information provided by the exporting country relevant to its sanitary measures subject to the equivalence determination;
  - b. To gather additional information on the exporting country's food inspection system that may be required by the importing country to undertake a judgement of equivalence of sanitary measures;
  - c. As an optional undertaking of the importing country to improve knowledge and confidence in the exporting country's food inspection system.
27. In preparing for an on-site visit, the importing country should consider:
- a. Limiting the scope of on-site activities to the food product or group of food products and the associated sanitary measures that are the subject of the equivalence determination
  - b. The desirability for agreement between the importing and exporting countries regarding protocols for on-site activities.

#### **Decision regarding a Judgement of equivalence<sup>15</sup>**

28. A decision regarding the judgement of equivalence could be made at several points including:
- a. At initial contact by the exporting country;
  - b. Following review of the submittal package by the importing country;
  - c. Following onsite visits by the importing country;
  - d. Following an assessment based on experience, knowledge and confidence;
  - e. Following an assessment based on an objective basis of comparison.
  - f. Following further exchange of information that resolves any differences of opinion.
29. Equivalence of sanitary measures proposed by the exporting country should be granted by the importing country when:
- a. The experience, knowledge and confidence of the importing country with the pertinent measures of the exporting country is such that the importing country can determine that measures are equivalent;
  - b. The exporting country demonstrates, through the use of the objective basis of comparison, that its alternative measures are equivalent to those of the importing country. This comparison is facilitated with the use of quantitative data but also can be done on a qualitative basis.

---

<sup>13</sup> Paragraph 32 of this document deals with Technical Assistance With Respect To Equivalence Determinations

<sup>14</sup> Additional guidance elaborating on paragraph 7, k) of the main document.

<sup>15</sup> Additional guidance elaborating on Section 8 of the main document.

30. As agreed between the importing and exporting countries, the importing country should provide to the exporting country a written report as to whether or not equivalence has been found with respect to the exporting country's alternative measure/s. At any point in the process, an importing country should have the possibility in consultation with the exporting country and when evidence exists that equivalence is not possible, to stop the process. Where equivalence is not found, the reasoning for this should be given to the exporting country and should be included in the written report with suggestions for solutions where possible.

#### **TECHNICAL ASSISTANCE WITH RESPECT TO EQUIVALENCE DETERMINATIONS<sup>16</sup>**

31. Countries considering the need for technical assistance with respect to equivalence determinations or countries considering providing technical assistance, may wish to consider the following:
- Technical assistance is not a mandatory pre-requisite by either party in undertaking a determination of equivalence.
  - Appropriate areas for technical assistance associated with an equivalence determination could include:
    - assistance in evaluating which measures would be the subject of an equivalence determination;
    - assistance with the preparation of documentation, including the submittal package;
    - assistance in undertaking necessary risk assessments;
    - assistance with data analysis; and
    - assistance in assessing whether measures meet the importing country's stated objective basis of comparison.
  - It would not normally be expected that the governmental body responsible for evaluating the exporting country's equivalence proposal would provide technical assistance relating to broad infrastructure (e.g., improvements to food regulatory control systems, improvements to food production/processing systems).<sup>17</sup>
  - The request for technical assistance should normally come from the exporting country, usually a developing country, to the importing country, usually but not always, a developed country, as part of the initial request for an equivalence determination.

---

<sup>16</sup> Additional guidance elaborating paragraph 7, n) of the main document.

<sup>17</sup> Developing countries may, however, in their consideration of undertaking an equivalence determination, recognize the need for broad infrastructure enhancements and seek technical assistance to undertake such enhancements from other entities (e.g., national technical assistance agencies, international development banks, etc.)

## Attachment 2

**LIST OF PARTICIPANTS  
LISTE DES PARTICIPANTS  
LISTA DE PARTIPANTES**

**ARGENTINA**

Ms Gabriela Alejandra Catalani  
Coordinadora Tecnica Pto Focal del Codex  
Secretaria de Agricultura, Ganaderia  
Pesca y Alimentacion, Paseo Colon 922 of 29  
1063 BUENOS AIRES  
ARGENTINA  
Phone: +54 11 4349 2549  
Fax: +54 11 4349 2549  
Email: [codex@mecon.gov.ar](mailto:codex@mecon.gov.ar)  
Alternate Email: [gcatal@mecon.gov.ar](mailto:gcatal@mecon.gov.ar)

**AUSTRALIA**

Mr. Gregory Read  
Executive Manager  
Exports and Corporate Division  
Australian Quarantine and Inspection Service  
Australian Government Department of  
Agriculture Fisheries and Forestry  
GPO Box 858  
CANBERRA ACT 2601  
AUSTRALIA  
Phone: +61 2 6272 3594  
Fax: +61 2 6272 4112  
Email: [gregory.read@daff.gov.au](mailto:gregory.read@daff.gov.au)

Mr. Mark Schipp  
General Manager, Market Maintenance  
Australian Quarantine and Inspection Service  
Australian Government Department of  
Agriculture Fisheries and Forestry  
GPO Box 858  
CANBERRA ACT 2601  
AUSTRALIA  
Phone: +61 2 6272 5254  
Fax: +61 2 6271 6522  
Email: [mark.schipp@daff.gov.au](mailto:mark.schipp@daff.gov.au)

Ms Claire Pontin  
General Manager, Food Safety and Services  
Food Standards Australia New Zealand  
Level 2, 55 Blackall Street  
BARTON ACT 2600  
AUSTRALIA  
Phone: +61 2 6271 2202  
Fax: +61 2 6271 2261  
Email: [claire.pontin@foodstandards.gov.au](mailto:claire.pontin@foodstandards.gov.au)

Ms Ann Backhouse  
Manager, Codex Australia  
Product Safety and Integrity  
Australian Government Department of  
Agriculture, Fisheries and Forestry  
GPO Box 858  
CANBERRA ACT 2601  
AUSTRALIA  
Phone: +61 2 6272 5692  
Fax: +61 2 6272 3103  
Email: [ann.backhouse@daff.gov.au](mailto:ann.backhouse@daff.gov.au)

**BRAZIL**

Dr Marcelo Bonnet  
Director, Plant Products Inspection Department  
Ministry of Agriculture, Animal Production and  
Food Supply  
Esplanada dos Ministerios  
BL D Ala B sala 337  
BRASILIA  
BRAZIL  
Phone: +55 61 3218 2323  
Fax: +55 61 3226 9842  
Email: [mbonnet@agricultura.gov.br](mailto:mbonnet@agricultura.gov.br)

Mrs Laura Misk de Faria Brant  
Technical Assistant  
National Health Surveillance Agency  
SEPN 511 Bloco A  
ED Bittar II  
BRASILIA  
BRAZIL  
Phone: +55 61 3448 6277  
Fax: +55 61 3448 6274  
Email: [gicra@anvisa.gov.br](mailto:gicra@anvisa.gov.br)

Mrs Ana Virginia de Almeida Figueiredo  
Manager of Food Inspection  
Brazilian National Health Surveillance Agency  
Ministry of Health  
Sepn 511 Bloco A  
EDIFICIO Bittar II 2° ANDAR  
BRASILIA- DF  
BRAZIL  
Phone: +55 61 3448 6277  
Fax: +55 61 3448 6274  
Email: [ana.virginia@anvisa.gov.br](mailto:ana.virginia@anvisa.gov.br)

Miss Denise Obara  
 Advisor, International Affairs Office  
 National Health Surveillance Agency  
 SEPN 515, Bloco B, Ed. Omega 4 andar  
 70770-502 Brasilia – DF  
 BRAZIL  
 Phone:+55 61 3448 1078  
 Fax:+55 61 3448 1089  
 Email: [rel@anvisa.gov.br](mailto:rel@anvisa.gov.br)

Mr Daniel Santos Tavares  
 Coordinator of Certification  
 Department of Inspection of Animal Origin  
 Products, Ministry of Agriculture, Livestock and  
 Food Supply  
 Esplanada dos Ministerios  
 BL D Ala B sala 337  
 BRASILIA  
 BRAZIL  
 Phone:+55 61 3218 2684  
 Fax:+55 61 3218 2672  
 Email: [Danielsantos@agricultura.gov.br](mailto:Danielsantos@agricultura.gov.br)

Miss Rosana Vasconcellos  
 Inspector, Ministry of Agriculture, Livestock and  
 Food Supply  
 Esplanada Dos Ministerios  
 Bloco D Anexo B, Sala 337  
 CEP 70043-900  
 BRAZIL  
 Phone:+55 61 3218 2323  
 Fax:+55 61 3226 9842  
 Email: [rosanar@agricultura.gov.br](mailto:rosanar@agricultura.gov.br)

## CANADA

Dr Thomas Feltmate  
 Manager, Food Safety Risk Analysis  
 Canadian Food Inspection Agency  
 ADRI-CPQP Floor 3, Room C311  
 3851 Fallowfield Road  
 Po Box 11300  
 OTTAWA ONTARIO K2H 8P9  
 CANADA  
 Phone:+1 613 228 6698 ext. 5982  
 Fax:+1 613 228 6675  
 Email: [tfeltmate@inspection.gc.ca](mailto:tfeltmate@inspection.gc.ca)

## EUROPEAN COMMUNITY

Mr Alain Dehove  
 Administrator, Health and Consumer Protection  
 Directorate-General  
 European Commission  
 F101 02/60  
 BRUSSELS B-1049  
 BELGIUM  
 Phone:+32 2 295 2538  
 Fax:+ 32 2 299 8566  
 Email: [alain.dehove@ec.europa.eu](mailto:alain.dehove@ec.europa.eu)

Mr Nicolas Guth  
 Health and Consumer Protection Directorate-  
 General  
 European Commission  
 B232 02/66  
 BRUSSELS B-1049  
 BELGIUM  
 Phone:+32 2 298 4681  
 Fax:  
 Email: [nicolas.guth@ec.europa.eu](mailto:nicolas.guth@ec.europa.eu)

Ms Bernadette Klink Khachan  
 Coordinator, Health and Consumer Protection  
 Directorate-General European Commission  
 F101 02/64  
 BRUSSELS 1049  
 BELGIUM  
 Phone:+32 2 295 7908  
 Fax:+32 2 299 8566  
 Email: [bernadette.klink-khachan@ec.europa.eu](mailto:bernadette.klink-khachan@ec.europa.eu)

Dr Jérôme Lepeintre  
 Administrator, Health and Consumer Protection  
 Directorate-General  
 European Commission  
 F101 02/62  
 BRUSSELS B-1049  
 BELGIUM  
 Phone:+32 2 2993701  
 Fax:+32 2 2998566  
 Email: [jerome.lepeintre@ec.europa.eu](mailto:jerome.lepeintre@ec.europa.eu)

Mr Michael Scannell  
 Head of Unit, Health and Consumer Protection  
 Directorate-General  
 European Commission  
 F101 02/54  
 BRUSSELS B-1049  
 BELGIUM  
 Phone:+32 2 299 3364  
 Fax:+32 2 299 8566  
 Email: [Michael.Scannell@ec.europa.eu](mailto:Michael.Scannell@ec.europa.eu)

Mr Philip Landon  
Administrator, General Secretariat of the Council  
of the European Union  
Rue de la Loi 175  
B-1048, BRUSSELS  
BELGIUM  
Phone:+32 2 235 4966  
Fax:+32 2 285 7928  
Email: [philip.landon@consilium.eu.int](mailto:philip.landon@consilium.eu.int)

Mr Kari Tölliö  
Principal Administrator  
General Secretariat of the Council of European  
Union  
Rue de la Loi 175 B- 1048  
BRUSSELS  
BELGIUM  
Phone:+32 2 281 7841  
Fax:  
Email: [kari.tollikko@consilium.eu.int](mailto:kari.tollikko@consilium.eu.int)

#### **FINLAND**

Mrs Hentriikka Kontio  
Veterinary Counsellor Ministry of  
Agriculture and Forestry  
Department of Food and Health  
PO Box 30  
HELSINKI FI-00023  
FINLAND  
Phone:+358 9 160 52432  
Fax:+358 9 160 52779  
Email: [Hentriikka.Kontio@mmm.fi](mailto:Hentriikka.Kontio@mmm.fi)

Ms Leena Eerola  
Veterinary Officer, Ministry of Agriculture and  
Forestry  
Department of Food and Health  
PO Box 30  
HELSINKI FI-00023  
FINLAND  
Phone:+358 9 1605 2943  
Fax:+358 9 1605 2779  
Email: [Leena.Eerola@mmm.fi](mailto:Leena.Eerola@mmm.fi)

#### **FRANCE**

Mrs Roseline Lecourt  
Chargée de Mission  
Ministère de l'Economie des Finances et de  
l'Industrie  
DGCCRF  
59 Boulevard Vincent Auriol  
75703 PARIS CEDEX 13  
FRANCE  
Phone:+33 01 4497 34 70  
Fax:+33 01 44 97 30 37  
Email: [roseline.lecourt@dgccrf.finances.gouv.fr](mailto:roseline.lecourt@dgccrf.finances.gouv.fr)

Miss Catherine Chapoux  
Chargée d'Etudes  
Ministère de L'Agriculture de L'Alimentation  
de la Pêche et des Affaires Rurales  
DGAL 251 rue de Vaugirard  
75732 PARIS CEDEX 15  
FRANCE  
Phone:+33 01 49 55 8486  
Fax:+33 01 49 55 44 62  
Email: [catherine.chapoux@agriculture.gouv.fr](mailto:catherine.chapoux@agriculture.gouv.fr)

#### **GERMANY**

Dr Antje Jaensch  
Federal Office of Consumer Protection and Food  
Safety  
Taubenstr 42-43, D-10117  
Berlin  
GERMANY  
Phone: +49 1888 413 3169  
Fax: +49 1888 413 3366  
Email: [antje.jaensch@bvl.bund.de](mailto:antje.jaensch@bvl.bund.de)

#### **GREECE**

Mr Vasileios Kontolaimos  
Legal Advisor  
Greek Ministry of Rural Development and Food  
29 Acharnon Street 10439  
ATHENS  
GREECE  
Phone:+302 1082 50307  
Fax:+302 1082 54621  
Email: [cohalka@otenet.gr](mailto:cohalka@otenet.gr)

Mr Vasileios Gkatzios  
 Official Veterinarian  
 Hellenic Food Authority  
 KIFISIAS 124 & IATRIDOU 2  
 11526  
 ATHENS  
 GREECE  
 Phone: +302106971685  
 Fax: +302106971501  
 Email: [vgatzios@efet.gr](mailto:vgatzios@efet.gr)

**ITALY**

Mr Ciro Impagnatiello  
 Ministero delle politiche agricole e forestali  
 Via XX Settembre 20  
 ROMA 00187  
 ITALY  
 Phone: +39 06 46656511  
 Fax: +39 06 4880 273  
 Email: [c.impagnatiello@politicheagricole.it](mailto:c.impagnatiello@politicheagricole.it)

Dr Piergiuseppe Facelli  
 Dirigente Veterinario  
 Ministero Della Salute  
 Piazza Marconi, 25, 1-00144  
 ROMA  
 ITALY  
 Phone: +39 06 5994 6828  
 Fax: +39 06 5994 6253  
 Email: [pg.facelli@sanita.it](mailto:pg.facelli@sanita.it)

**JAPAN**

Dr Toshitaka Higashira  
 Section Chief  
 Inspection and Safety Division, Department of  
 Food Safety  
 Ministry of Health, Labour and Welfare  
 1-2-2 Kasumigaseki, Chiyoda-ku  
 Tokyo, 100-8916  
 JAPAN  
 Phone: +81 3 3595 2337  
 Fax: +81 3 3503 7964  
 Email: [higashira-toshitaka@mhlw.go.jp](mailto:higashira-toshitaka@mhlw.go.jp)

Mr Hideya Yamada  
 Deputy Director  
 Food Safety and Consumer Policy Division  
 Ministry of Agriculture, Forestry & Fisheries  
 1-2-2 Kasumigaseki, Chiyoda-ku  
 Tokyo, 100-8916  
 JAPAN  
 Phone : +81 3 5512 2291  
 Fax : +81 3 3597 0329  
 Email: [hideya\\_yamada@nm.maff.go.jp](mailto:hideya_yamada@nm.maff.go.jp)

**KENYA**

Dr James Karitu  
 Assistant Director of Veterinary Services  
 Department of Veterinary Services  
 Ministry of Livestock and Fisheries  
 Box 00625, Kangemi  
 NAIROBI  
 KENYA  
 Phone: +254 020 631 390  
 Fax: +254 020 631 273  
 Email: [jkaritu@dvskabete.go.ke](mailto:jkaritu@dvskabete.go.ke)

**LATVIA**

Mrs Lauska Dace  
 Senior Officer  
 Veterinary and Food Department  
 Ministry of Agriculture, Republic of Latvia  
 Republikas laukums 2  
 RIGA  
 LV-1981  
 LATVIA  
 Phone: +371 702 7264  
 Fax: +371 702 7205  
 Email: [dace.lauska@zm.gov.lv](mailto:dace.lauska@zm.gov.lv)

**MALAYSIA**

Dr Moktir Singh s/o Gardir Singh  
 Senior Veterinary Officer  
 Department of Veterinary Services Malaysia  
 Ministry of Agriculture and Agro-Based Industry  
 Wisma Tani, Podium Block 1A  
 Lot 4G1, Precinct 4  
 Federal Government Administrative Centre  
 62630 PUTRAJAYA  
 MALAYSIA  
 Phone: +603 8870 2123  
 Fax: +603 8888 5755  
 Email: [moktir@jph.gov.my](mailto:moktir@jph.gov.my)

**MEXICO**

Dr Marcela Fuentes  
 Directora de Inspeccion en Puertos  
 Aeropuertos y Fronteras  
 Secretaria de Agricultura Ganaderia Desarrollo  
 Rural Pesca y Alimentacion Municipio Libre  
 377 DISTRITO FEDERAL 03310  
 MEXICO  
 Phone: +52 55 918 31000 Ext. 34080  
 Email: [eic.dgif@senasica.sagarpa.gob.mx](mailto:eic.dgif@senasica.sagarpa.gob.mx)

**NETHERLANDS**

Ms Inge Hamid- Hardenberg  
 Senior Policy Officer  
 Netherlands Ministry of Agriculture, Nature and  
 Food Quality  
 P.O. Box 20401  
 2500 EK The Hague  
 NETHERLANDS  
 Phone:+31 70 3785435  
 Fax:+31 70 3786134  
 Email: [i.hamid-hardenberg@minlnv.nl](mailto:i.hamid-hardenberg@minlnv.nl)

**NEW ZEALAND**

Dr Steve Hathaway  
 Director, Science  
 New Zealand Food Safety Authority  
 86 Jervois Quay  
 PO Box 2835  
 Wellington  
 NEW ZEALAND  
 Phone:+64 6 867 1144  
 Fax: + 64 6 868 5207  
 Email: [steve.hathaway@nzfsa.govt.nz](mailto:steve.hathaway@nzfsa.govt.nz)

**NORWAY**

Mr Lennart Johanson  
 Deputy Director General  
 Norwegian Ministry of Fisheries  
 PO Box 8118 Dep NO- 0032  
 OSLO  
 NORWAY  
 Phone:+47 2224 2665  
 Fax:+47 2224 5678  
 Email: [Lennart.Johanson@fkf.dep.no](mailto:Lennart.Johanson@fkf.dep.no)

Mrs Tone Elisabeth Matheson  
 Senior Adviser, Codex Manager  
 Section for International and Legal Coordination  
 Department of Operations Policy  
 Norwegian Food Safety Authority  
 BRUMUNDAL  
 NORWAY  
 Phone:+47 2321 6651  
 Fax:+41 2321 6801  
 Email: [tone.elisabeth.matheson@mattilsynet.no](mailto:tone.elisabeth.matheson@mattilsynet.no)

**PERU**

Mr Jorge Jallo  
 Consejero  
 Embajada del Peru en el Reino de Belgica  
 Avenue de Tervueren 179  
 1150 Bruselas  
 BELGICA  
 Phone:+32 2733 3185  
 Fax:  
 Email: [codex@digesa.minsa.gob.pe](mailto:codex@digesa.minsa.gob.pe)

**THAILAND**

Ms Usa Bamrungbhuet  
 Standard Officer, Office of Commodity and  
 System Standards  
 National Bureau of Agricultural Commodity and  
 Food Standards  
 3 Rajdamnern Nok Avenue  
 BANGKOK 10200  
 THAILAND  
 Phone:+66 2283 1600 Ext. 1184  
 Fax:+66 2 280 3899  
 Email: [usa@acfs.go.th](mailto:usa@acfs.go.th)

Cholawit Chulabutra  
 First Secretary, Agriculture  
 Office of Agricultural Affairs  
 Royal Thai Embassy  
 Ave. Franklin Roosevelt 184  
 B-1050 Brussels  
 BELGIUM  
 Phone:+322 660 6069  
 Fax:+322 672 6437  
 Email: [agrithai@skynet.be](mailto:agrithai@skynet.be)

Ms Pasinee Napombejra  
 Secondary Secretary, Agriculture  
 Office of Agricultural Affairs  
 Royal Thai Embassy  
 Ave. Franklin Roosevelt 184  
 B-1050 Brussels  
 BELGIUM  
 Phone:+322 660 6069  
 Fax:+322 672 6437  
 Email: [agrithai@skynet.be](mailto:agrithai@skynet.be)



**UNITED STATES OF AMERICA**

Dr Catherine Carnevale  
Director, International Affairs  
Centre for Food Safety and Applied Nutrition,  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park  
MARYLAND 20740  
USA  
Phone:+1 301 436 1723  
Fax:+1 301436 2618  
Email: [catherine.carnevale@fda.hhs.gov](mailto:catherine.carnevale@fda.hhs.gov)

Ms Edith Kennard  
Staff Officer, US Codex Office/ FSIS /  
USDA, 1400 Independence Avenue  
SW, Room 4861 South Building  
WASHINGTON DC 20250  
USA  
Phone:+1 202 720 5261  
Fax:+1 202 720 3157  
Email: [edith.kennard@fsis.usda.gov](mailto:edith.kennard@fsis.usda.gov)

Ms Karen Stuck  
Assistant Administrator  
Food Safety and Inspection Service  
Office of International Affairs  
Department of Agriculture  
1400 Independence Avenue SW  
Room 3143 - South Building  
WASHINGTON DC 20250  
USA  
Phone:+1 202 720 3473  
Fax:+1 202 720 7990  
Email: [karen.stuck@fsis.usda.gov](mailto:karen.stuck@fsis.usda.gov)

Dr H. Michael Wehr  
Codex Program Coordinator  
Centre for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park MD  
MARYLAND 20740  
USA  
Phone:+1 301 436 1724  
Fax:+1 301 436 2618  
Email: [michael.wehr@fda.hhs.gov](mailto:michael.wehr@fda.hhs.gov)

**INTERNATIONAL NON- GOVERNMENT ORGANIZATIONS****INTERNATIONAL ASSOCIATION OF CONSUMER FOOD ORGANIZATIONS**

Mr Bruce Silverglade  
President  
International Association of Consumer Food  
Organisations  
1875 Connecticut Avenue, NW  
Suite 300  
Washington DC 20009  
USA  
Phone:+1 202 777 8337  
Fax:+1 202 265 4954  
Email: [bsilverglade@cspinet.org](mailto:bsilverglade@cspinet.org)

**CODEX SECRETARIAT**

Ms Annamaria Bruno  
Food Standards Officer  
Food and Nutrition Division  
Joint FAO/WHO Food Standards  
Programme, Viale delle Terme di Caracalla  
0100 ROME  
ITALY  
Phone:+39 06 5705 6254  
Fax:+39 06 5705 4593  
Email: [annamaria.bruno@fao.org](mailto:annamaria.bruno@fao.org)